Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

variable alongside price differential. ***Conclusions:*** This model better applies to non-orphan originators. Despite compelling R-square values, results are limited by the low sample size. Biosimilar pricing is more influential than originator step therapy requirements on market share. The difference between non-orphan originator prices and the average price of their biosimilar(s) was the only variable able to predict market share across all statistically significant model scenarios. Other variables such as the number of biosimilars, the duration of biosimilar competition, and step therapy requirements also partly influence market share. Perhaps, the number of biosimilars and duration of competition may influence price differentials. Similarly, price differentials may affect payer management decisions such as step therapy requirements.

EE315
TRENDS IN MEDICAL EXPENDITURE AND RESOURCE UTILIZATION AMONG OPIOID, BENZODIAZEPINE, SKELETAL MUSCLE RELAXANT, AND GABAPENTIN USERS: A POOLED CROSS SECTIONAL ANALYSIS FROM 2009 - 2019

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Objectives: To evaluate health expenditure and emergency department use associated with non-opioid analgesic, opioid-only, opioid+benzodiazepine (OP/BZD), opioid+benzodiazepine+skeletal muscle relaxant (OP/BZD/SMR), and opioid+gabapentin (OP/GABA) users in the US from 2009-2019. ***Methods:*** We performed a pooled serial cross-sectional analysis using nationally representative data from 2009-2019 of the Medical Expenditure Panel Survey. We evaluated differences in annual healthcare expenditures (total, inpatient, outpatient, emergency department, prescription) and ED utilization between users reporting non-opioid analgesics only, opioids only, OPI/BZD, OPI/BZD/SMR, and OP/GABA. A generalized linear model with a gamma distribution and interaction terms between treatment group and year was fitted to estimate differences in yearly changes in expenditure across treatment groups. We used survey weights to derive nationally representative estimates. ***Results:*** A weighted total of 163,892,872 non-opioid users, 175,076,188 opioid-only users, 19,826,350 OP/BZD users, 4,815,304 OP/BZD/SMR users, 13,049,509 OP/GABA users were included in our sample. Compared to non-opioid analgesic users, OP/GABA users had the greatest adjusted annual expenditures (RR=2.99, 95% CI:2.60-3.11) and the highest annual increase in average total expenditure per year compared to non-opioid users (coefficient=$1,231.41, 95%CI:$492.50-$1,970.33). OP/BZD/SMR users had higher rates of ED utilization compared to non-opioid users (RR=2.60,95%CI:1.64-2.60). ***Conclusions:*** OP/GABA users had higher healthcare expenditure and rates of expenditure increase over time compared to non-narcotic users from 2009-2019. OP/BZR/SMR users had higher rates of ED use compared to non-narcotic users. These results may inform health policy initiatives that seek to reduce unnecessary opioid use in patients using other medications associated with opioid misuse.

EE316
COST-EFFECTIVENESS OF PRETOMANID-BASED REGIMEN FOR TREATMENT OF HIGHLY DRUG-RESISTANT TUBERCULOSIS IN A HIGH-INCOME COUNTRY

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Objectives: Treatment for highly resistant tuberculosis (HDR-TB) with bedaquiline-linezolid-based regimen is costly, takes a long time to complete, and has potentially life-threatening adverse effects. Recent clinical findings reported improvement in clinical outcomes of HDR-TB with the pretomanid-based regimen (with shortened treatment duration). This study aimed to evaluate the cost-effectiveness of the pretomanid-based regimen for HDR-TB treatment from the perspective of healthcare provider in the US. ***Methods:*** A 2-year decision-analytic model was constructed to simulate potential treatment outcomes of (1) bedaquiline-pretomanid-linezolid (BPaL) regimen), and (2) bedaquiline-linezolid (B-L) based regimen in a hypothetical cohort of adult patients with active HDR-TB. The model inputs were retrieved from literature and public data. Primary model outputs were TB-related direct medical cost, disability-adjusted life-years (DALYs), and incremental cost per DALY averted (ICER). Base-case and sensitivity analyses were performed. ***Results:*** In the base-case analysis, the BPaL regimen averted 2.5511DALYs and saved cost by USD53,502 when compared to the B-L-based regimen. No influential parameter with threshold value was identified in the one-way sensitivity analysis. In the probabilistic sensitivity analysis of 10,000 Monte Carlo simulations, the BPaL regimen reduced DALYs by 2.2974 (95%CI 2.2802-2.3146; $p<0.001$) with a cost saving of USD53,072 (95%CI USD51,366-USD54,778; $p<0.001$). The BPaL regimen reduced DALYs at lower cost in 75.51% of the time, and averted DALYs at higher cost with ICER less than willingness-to-pay (WTP) threshold (100,000 USD/DALY) in 24.08% of the simulations. The probability of the BPaL regimen to be cost-effective was higher than the B-L-based regimen throughout the variation of WTP, and it was 99.59% at the WTP threshold of 100,000 USD/DALY. ***Conclusions:*** The BPaL therapy appeared to be effective in averting DALYs at reduced cost, with a high probability to be accepted as the preferred cost-effective option for HDR-TB treatment from the perspective of US healthcare provider.

EE317
EXAMINING ICER'S INCLUSION OF NOVEL VALUE FACTORS: DO THEY MOVE THE NEEDLE ON VALUE APPRAISALS?

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Objectives: To assess the extent to which novel value factors are incorporated in ICER assessments and influence appraisal committee (AC) long-term value for money (LTVM) votes. ***Methods:*** We identified reports assessing pharmaceutical interventions published between 10/2017 and 10/2022, excluding those without an appraisal committee meeting (N=40). We extracted data on interventions, comparators, cost/QALY estimates, AC voting questions, and votes. We identified novel value factors in the questions and calculated inclusion frequency and average voting score for each factor across all reports. For each intervention/comparator, we categorized ICER's cost-effectiveness value for money (CEVM) estimate as high-value ($0 - $50,000 cost/QALY), intermediate-value ($51,000 - $175,000 cost/QALY), or low-value (> $175,00 cost/QALY) and compared it to the distribution of AC LTVM votes. ***Results:*** 22 novel factors were identified in AC votes. Factors most frequently included were caregiver impact (n=38 reports), disease severity (n=37), lifetime burden of illness (n=36), and health equity (n=29). Novel factor inclusion was inconsistent, partly due to the impact of ICER's evolving assessment framework on AC voting questions and response scales. Across all reports, high average AC voting scores indicated lifetime burden of illness, novel mechanism of action, and regimen complexity were often identified as impactful when evaluating LTVM. Conversely, treatment ability to reduce health inequities received neutral scores. LTVM votes often differed from CEVM categorizations, suggesting novel factors have some impact: high-value CEVM treatments received 23% high, 55% intermediate, 12% low LTVM votes; intermediate-value CEVM received 17% high, 58% intermediate, 24% low LTVM votes; low-value CEVM received 2% high, 22% intermediate, 76% low LTVM votes. ***Conclusions:*** Novel factor inclusion is inconsistent across ICER reports. Lifetime burden of illness was often included and earned a high average AC voting score, while health equity considerations earned a low score. Differences in CEVM and LTVM categorizations indicate that novel factors likely have some impact on AC votes.

EE318
TRENDS IN PRICES OF NEW ORAL DRUGS FOR CHRONIC USE APPROVED BY THE FDA (1980-2021)

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Objectives: To assess the trends and factors associated with the price at market entry of new molecular entities (NMEs) with oral formulations and chronic use approved by the FDA between 1980 and 2021. ***Methods:*** Data on regulatory information, defined daily dosages, and wholesale acquisition cost (WAC) at market entry were extracted from the FDA, World Health Organization, and IBM Micromedex, respectively. WAC was used as a proxy for private sector prices, as both Medicaid and the Federal Supply Schedule use WAC to estimate rebates and reimbursement for new drugs at market entry. Prices were converted to average 2021 US dollars using the consumer price index. Descriptive statistics and regression analysis were conducted. ***Results:*** The FDA approved 436 new drugs with oral formulations for chronic use from 1980 to 2021. Among these, 121 (27.1%) had orphan designation, 210 (47.1%) were approved using the FDA priority review designation, and 210 (47.1%) had generic competition as of December 2021. The median inflation-adjusted price per year at market entry was $923 (IQR=$872) in the 1980s (n=66, 15.1%), $1,467 (IQR=$3,134) in the 1990s (n=130, 29.8%), $2,434 (IQR=$9,924) in the 2000s (n=75, 17.2%), $76,390 (IQR=$138,847) in the 2010s (n=128, 29.4%), and $219,219 (IQR=$319,039) in 2020-2021 (n=37, 8.5%). The price at market entry per year was positively associated with orphan drug designation (2.64, $p<0.001$), priority review designation (0.63, $p<0.001$), approval date (0.1, $p<0.001$), antineoplastic and immunomodulating agents (4.71, $p<0.001$), anti-infectives for systemic use (2.54, $p<0.001$), nervous system (0.35, $p=0.04$), and alimentary tract and metabolism (0.58, $p=0.01$). ***Conclusions:*** This study observed a significant upward trend in the prices at market entry of new molecular entities approved by the FDA between 1980 and 2021. The approval date, orphan drug and priority review designations, and drugs for oncology and viral infections were associated with a higher price at market entry.

EE319
HEALTHCARE RESOURCE UTILIZATION AND DIRECT MEDICAL COSTS ASSOCIATED WITH POST COVID-19 CONDITION IN COLOMBIA, 2020-2021

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Objectives: This study aimed to estimate the direct medical costs of patients with post COVID-19 condition in a Colombian insurance company with more than 2.5 million affiliates. ***Methods:*** We conducted a bottom-up cost-of-illness study of adults with persistent symptoms after at least three months of hospital discharge due to COVID-19. We surveyed patients that were hospitalized between March 2020 and August 2021. We asked about healthcare resource utilization (HCRU), which included laboratories and images, medications, consults, rehospitalizations, and others, associated with post COVID-19 condition. The answers were verified using the company's outpatient and inpatient service authorization records. Costs were estimated from the third payer perspective and expressed in American dollars using an exchange rate of 1USD$=3,743COP. ***Results:*** We included 202 participants, 51.5% were male, mean age of 55.6 years old, 49% had a comorbidity (41.9% hypertension), and 46 patients (22.8%) required an intensive care unit. A total of 159 (78.7%) patients reported at least one symptom after discharge. Of these, 132 (65.3%) persisted with at least one symptom during the telephone survey. Seventy-five (47.2%) of the 159 patients with persistent symptoms reported HCRU. Of these, 93.3% consulted a physician (mean consultations: 2.1 SD 1.1; mean consultations with specialists: 2.4 SD 2.0), and 9.3% were re-hospitalized. The average direct medical costs of post COVID-19 condition were US$824 (95% CI 195-1,454). Costs in outpatient were US$373 (95%CI 158-588), and in inpatient, US$3,285 (95%CI -167-6,738). ***Conclusions:*** It is crucial to follow up and identify patients discharged from the hospital who persist with symptoms after three months since we observed a greater HCRU, including prolonged recovery therapies

EE320
COST-EFFECTIVENESS OF CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPIES FOR BLOOD CANCERS: A SYSTEMATIC REVIEW

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Objectives: This review aims to review existing evidence on the cost-effectiveness of the six CAR T-cell therapies across different international jurisdictions. ***Methods:*** We conducted a systematic review using PubMed, Scopus and Web of Science databases to identify economic evaluations published until 29 November 2022. The methodological quality of each study was assessed using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), 2022 edition. Studies were included if they were full economic evaluations (within-trial and model-based). Extracted data was grouped according to type of CAR T-cell therapy and summarised narratively. ***Results:*** The review included 29 full cost-effectiveness studies: tisagenlecleucel (n = 14), axicabtagene ciloleucel (n = 6), axicabtagene ciloleucel with tisagenlecleucel (n = 3), brexucabtagene autoleucel (n = 4), and lisocabtagene maraleucel (n = 2). Incremental costs varied considerably between $US1407 and $US606,010, whereas QALYs gained ranged from 0.81 to 10.77 over a lifetime horizon. The highest incremental QALY was reported for tisagenlecleucel in the Netherlands, Singapore and Spain; 10.77, 9.87 and 8.97 for use in paediatric, relapsed/refractory B-cell acute lymphoblastic leukaemia (ALL). The highest incremental cost ($US606,010) was associated with the use of axicabtagene ciloleucel therapy in Canada for diffuse large B-cell lymphoma (DLBCL) and US (US$439,500), and brexucabtagene autoleucel for mantle cell lymphoma in the UK (US$367,423). The main cost-driver of the total cost were attributed to the price of the CAR T-cell therapy. ***Conclusions:*** To our knowledge, this is the most up-to-date literature review on the cost-effectiveness of existing CAR T-cell therapies. It finds uncertainty was not limited to evidence generation but extended to the affordability of CAR T-cell therapies. Existing reimbursement models for CAR T-cell therapies are not fit for propose. This review highlights the need for robust evidence to address considerable uncertainty in the cost and effectiveness data given the magnitude of differences in cost-effectiveness estimates.

EE321
COST IMPACT OF NEXT GENERATION SEQUENCING TESTING IN NSCLC WITH AND WITHOUT RNA SEQUENCING

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Objectives: Identifying cancer patients who may benefit from targeted therapies is essential for treatment decisions. Due to the large number of potential oncogenic drivers in advanced non-small cell lung cancer (NSCLC), next-generation sequencing (NGS) is guideline-recommended for identifying actionable targets to inform treatment decisions. Multiple testing options incorporating DNA and/or RNA sequencing are available. Given the potential for improved detection of actionable fusions using RNA sequencing, we examined the costs associated with these testing options. ***Methods:*** A Microsoft Excel-based model was developed to evaluate patients diagnosed with advanced/metastatic NSCLC. Treatment pathways were based on NCCN guidelines and expert opinion. Economic inputs were estimated for one year based on published literature, including cost of NGS testing based on a generic CPT code, treatment costs, and productivity losses. A range of 2.5-14% was considered for the rate of fusions detected by RNA but not DNA sequencing. Outputs included the number of actionable fusions identified and costs. Results were estimated for patients receiving NGS testing with DNA-only sequencing with/without reflex RNA testing and DNA+RNA sequencing. ***Results:*** Based on the model, tests that include RNA sequencing increased the number of fusions identified compared with DNA sequencing alone without reflex RNA testing. Use of reflex RNA testing increased costs per NSCLC patient compared with upfront DNA+RNA sequencing, with cost savings ranging from $349 at the 2.5% level to $741 at the 14% level of additive detection. ***Conclusions:*** In advanced NSCLC, NGS tests that include DNA and RNA sequencing identify those eligible for targeted therapies more efficiently, depending on the additive detection rate of fusions by RNA-sequencing. Upfront DNA+RNA testing also reduces both costs and turn-around-time compared with initial DNA sequencing followed by reflex RNA sequencing. Further investigations into the advantages of RNA sequencing are warranted.

EE322
COST-EFFECTIVENESS ANALYSIS OF INTRAOPERATIVE NEUROMONITORING VERSUS VISUAL IDENTIFICATION OF RECURRENT LARYNGEAL NERVE IN TOTAL THYROIDECTOMY

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Objectives: Recurrent laryngeal nerve injury (RLNI) is one of the most serious complications of thyroid surgery. Intraoperative neural monitoring (IONM) has been widely applied and recommended to reduces RLNI by clinical guidelines in China. To evaluate the cost-effectiveness of IONM in total thyroidectomy from the Chinese societal perspective. ***Methods:*** A cost-effectiveness analysis was performed by constructing a decision tree-Markov model to compare IONM with visual identification in total thyroidectomy, from the Chinese societal perspective. Model inputs were obtained from published literatures and government websites, which published the prices of medical services. The probabilities of RLNI came from a prospective multicenter study. Both direct medical costs and indirect costs were included in the model. Costs and outcomes were estimated over 30-year time horizon and discounted at 5% annually. The incremental cost-effectiveness ratio (ICER) was estimated for the IONM group versus the visual identification group. One-way and probabilistic sensitivity analyses were conducted to assess robustness of the results. ***Results:*** In the base case of 30-year time horizon, compared with visual identification, using IONM led to an increase of 0.071 QALYs at an additional cost of $347.47, resulting in an ICER of $4,908.11/QALY gained. One-way sensitivity analyses showed that, utility values of no RLNI, the cost of total thyroidectomy with/without IONM, probabilities of permanent unilateral RLNI with/without IONM had a greater influence on the ICER. Probabilistic sensitivity analyses showed 86.14% chance that the ICER would be accepted under the GDP per capita of China in 2021. ($1 = CNY6.4515) ***Conclusions:*** Compared with visual identification, using IONM in total thyroidectomy is cost-effective for patients undergoing total thyroidectomy at a willingness-to-pay threshold of $12,551.50/QALY for China. Results were robust across sensitivity analyses. These findings suggest that IONM is a cost-effective approach worth considering for patients with total thyroidectomy.

EE323
IMPLICATIONS FOR UTILIZING A FEMALE EXTERNAL CATHETER (FEC) IN END-OF-LIFE PATIENTS – MODEL OF THE POTENTIAL IMPACT UPON INFORMAL, UNPAID CAREGIVER (IUC) BURDEN IN THE COMMUNITY SETTING

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Objectives: 1.72 million Medicare beneficiaries were enrolled in hospice care in 2020. Hospice care enrollment yields savings for payers for many categories of patient. Additionally, disenrollment in hospice has been found to result in higher Medicare expenditures. The majority of Medicare days associated with hospice care take place in the home – a challenge for IUCs as these patients typically present with numerous co-morbidities including urinary incontinence which affects 84% of hospice patients. A major reason for hospice patients' return to the hospital setting is caregiver burden. This analysis seeks to determine the hours that IUCs provide to end-of-life patients in the community. Further, this analysis estimates the percentage of time that could be saved with a novel FEC that has been found to reduce time expended in the care of female patients with urinary incontinence. ***Methods:*** A systematic literature review of published research (2007-2022, PubMed and Embase databases) assessed the workload of IUCs who provided end-of-life care to primarily community-dwelling, US-based patients in the last 6 to 12 months of life. The results were modeled against research on the daily caregiver time savings afforded by use of an FEC. ***Results:*** 71 records were identified. After exclusions, 5 records were analyzed. The weekly IUC burden averaged between 22.9 and 65.8 hours. A 2022 study of caregivers (N=205) found the middle tertile reported daily time savings with an FEC of 1 to 3. The model determined that IUCs, providing end-of-life care, could